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Signature Page)*

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

UNITED STATES OF AMERICA, <i>et al., ex rel.</i> JESSICA PENELOW and CHRISTINE BRANCACCIO,	:	
Plaintiffs,	:	Case No. 12-7758 (ZNQ)(JBD)
v.	:	
JANSSEN PRODUCTS, LP,	:	
Defendant.	:	

RELATORS' PROPOSED JURY INSTRUCTIONS

INSTRUCTION NO. 1

Now that you have been sworn, I have the following preliminary instructions for your guidance as jurors in this case.

You will hear the evidence, decide what the facts are, and then apply those facts to the law that I will give to you.

You and only you will be the judges of the facts. You will have to decide what happened. I play no part in judging the facts. You should not take anything I may say or do during the trial as indicating what I think of the evidence or what your verdict should be. My role is to be the judge of the law. I make whatever legal decisions have to be made during the course of the trial, and I will explain to you the legal principles that must guide you in your decisions. You must follow that law whether you agree with it or not.

Source: Third Circuit Model Civil Instruction 1.1.

INSTRUCTION NO. 2

This case is brought under a federal law called the False Claims Act. The False Claims Act allows a person, called the “Relator,” to bring an action in the name of the United States Government against persons or companies alleged to have violated the False Claims Act. Additionally, this case is brought under similar laws in twenty-six states and the District of Columbia, each of which have their own version of the False Claims Act that allow a Relator to pursue claims on behalf of the State or District. These include California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Washington, and the District of Columbia.

In this case, Jessica Penelow and Christine Brancaccio are the Relators. Relators allege that defendant Janssen Products LP violated the federal False Claims Act and state laws by engaging in off-label marketing and kickback schemes, which caused the submission of false claims to government health care programs for reimbursement. Specifically, with regard to off-label marketing, Relators allege that Defendant falsely marketed its HIV drug Prezista as being “lipid neutral,” “lipid friendly,” or as having a similar impact on lipids as a competitor drug, Reyataz, contrary to its FDA-approved label during the entire relevant period of 2006 to 2014, and as being suitable for treatment naïve patients prior to obtaining FDA approval for such patients in October 2008. Relators also allege that Defendant falsely marketed its HIV drug Intelence as being suitable for once-a-day dosing, when it was only approved for twice-a-day dosing, and suitable for treatment naïve patients, contrary to its FDA-approved label, during the entire relevant period.

Regarding kickbacks, Relators allege that Defendant paid prescribers to serve on a Speaker Program and paid for prescribers’ travel, meals, and hotel stays in order to induce them to prescribe or to increase prescriptions of its drugs Prezista and Intelence, and/or to reward them for doing so.

The prescriptions that resulted from the off-label marketing and kickback schemes were paid for by the government under Medicare, Medicaid, and the AIDS Drug Assistance Program (referred to as “ADAP”). Defendant denies these allegations.

The False Claims Act and its state analogues authorize the Government to recover damages caused by false or fraudulent claims. To find defendant Janssen liable under the False Claims Act and its state analogues, you must find that it was

more likely than not that Defendant caused claims to be submitted in violation of the False Claims Act arising from either off-label marketing or from violations of the Anti-Kickback Statute. Under the False Claims Act, a “claim” is any request or demand for money where Medicare, Medicaid, or ADAP provides any portion of the money requested.

Source: Third Circuit Model Civil Instruction 1.2; 31 U.S.C. § 3730(b)(1); 740 Ill. Comp. Stat. § 175/3 (Illinois); N.J. Rev. Stat. § 2A:32C-3 (New Jersey); Cal. Gov. Code 12651 *et seq.* (California); Conn. Gen. Stat. § 4-275(a) (Connecticut); Mass. Gen. Laws ch. 12, § 5B(a) (Massachusetts); Va. Code §§ 8.01–216.1 *et seq.* (Virginia); Nev. Rev. Stat. §§ 357.010 *et seq.* (Nevada); Tex. Hum. Res. Code §§ 36.001 *et seq.* (Texas); *United States ex rel. Gohil v. Sanofi U.S. Servs. Inc.*, 500 F. Supp. 3d 345, 357–62 (E.D. Pa. 2020).

INSTRUCTION NO. 3

Now, a few words about your conduct as jurors.

First, I instruct you that during the trial and until you have heard all of the evidence and retired to the jury room to deliberate, you are not to discuss the case with anyone, not even among yourselves. If anyone should try to talk to you about the case, including a fellow juror, bring it to my attention promptly. There are good reasons for this ban on discussions, the most important being the need for you to keep an open mind throughout the presentation of evidence. I know that many of you use cell phones, smart phones, and other portable electronic devices; laptops, netbooks, and other computers both portable and fixed; and other tools of technology, to access the internet and to communicate with others. You also must not talk to anyone about this case or use these tools to communicate electronically with anyone about the case. This includes your family and friends. You may not communicate orally with anyone about the case on your cell phone, smart phone, or portable or fixed computer or device of any kind; or use these devices to communicate electronically by messages or postings of any kind including e-mail, instant messages, text messages, text or instant messaging services such as Twitter, or through any blog, website, internet chat room, or by way of any other social networking websites or services including Facebook, LinkedIn, and YouTube.

If any lawyer, party, or witness does not speak to you when you pass in the hall, ride the elevator, or the like, remember it is because they are not supposed to talk or visit with you, either. That is why you are asked to wear your juror tags. It shows that you are someone who is not to be approached in any way.

Second, do not read or listen to anything related to this case that is not admitted into evidence. By that I mean, if there is a newspaper article or radio or television report relating to this case, do not read the article or watch or listen to the report. In addition, do not try to do any independent research or investigation on your own on matters relating to the case or this type of case. Do not do any research on the internet, for example. You are to decide the case upon the evidence presented at trial. In other words, you should not consult dictionaries or reference materials, search the internet, websites, blogs, or use any other electronic tools to obtain information about this case or to help you decide the case. Please do not try to find out information from any source outside the confines of this courtroom.

Again, do not reach any conclusion on the claims until all of the evidence is in. Keep an open mind until you start your deliberations at the end of the case.

Source: Third Circuit Model Civil Instruction 1.3.

INSTRUCTION NO. 4

During the trial it may be necessary for me to talk with the lawyers out of your hearing by having a bench conference. If that happens, please be patient.

We are not trying to keep important information from you. These conferences are necessary for me to fulfill my responsibility, which is to be sure that evidence is presented to you correctly under the law.

We will, of course, do what we can to keep the number and length of these conferences to a minimum. While we meet, I will invite you to stand up and stretch and take a short break or perhaps even call a recess if it is a lengthy issue, and permit you to go downstairs for a break.

I may not always grant an attorney's request for a conference. Do not consider my granting or denying a request for a conference as any indication of my opinion of the case or of what your verdict should be.

Source: Third Circuit Model Civil Instruction 1.4.

INSTRUCTION NO. 5

The evidence from which you are to find the facts consists of the following:

1. The testimony of the witnesses;
2. Documents and other things received as exhibits;
3. Any facts that are stipulated—that is, formally agreed to by the parties; and
4. Any facts that are judicially noticed—that is, facts that I say you must accept as true even without other evidence.

The following things are not evidence:

1. Statements, arguments, and questions of the lawyers for the parties in this case;
2. Objections by lawyers;
3. Any testimony I tell you to disregard; and
4. Anything you may see or hear about this case outside the courtroom.

You must make your decision based only on the evidence that you see and hear in court. Do not let rumors, suspicions, or anything else that you may see or hear outside of court influence your decision in any way.

You should use your common sense in weighing the evidence. Consider it in light of your everyday experience with people and events, and give it whatever weight you believe it deserves. If your experience tells you that certain evidence reasonably leads to a conclusion, you are free to reach that conclusion.

There are rules that control what can be received into evidence. When a lawyer asks a question or offers an exhibit into evidence, and a lawyer on the other side thinks that it is not permitted by the rules of evidence, that lawyer may object. This simply means that the lawyer is requesting that I make a decision on a particular rule of evidence. You should not be influenced by the fact that an objection is made. Objections to questions are not evidence. Lawyers have an obligation to their clients to make objections when they believe that evidence being offered is improper under

the rules of evidence. You should not be influenced by the objection or by the court's ruling on it. If the objection is sustained, ignore the question. If it is overruled, treat the answer like any other. If you are instructed that some item of evidence is received for a limited purpose only, you must follow that instruction.

Also, certain testimony or other evidence may be ordered struck from the record and you will be instructed to disregard this evidence. Do not consider any testimony or other evidence that gets struck or excluded. Do not speculate about what a witness might have said or what an exhibit might have shown.

Source: Third Circuit Model Civil Instruction 1.5.

INSTRUCTION NO. 6

There are two types of evidence that you may use in reaching your verdict. One type of evidence is called “direct evidence.” An example of “direct evidence” is when a witness testifies about something that the witness knows through his own senses—something the witness has seen, felt, touched, or heard or did. If a witness testified that he saw it raining outside, and you believed him, that would be direct evidence that it was raining. Another form of direct evidence is an exhibit where the fact to be proved is its existence or current condition.

The other type of evidence is called circumstantial evidence. “Circumstantial evidence” is proof of one or more facts from which you could find another fact. If someone walked into the courtroom wearing a raincoat covered with drops of water and carrying a wet umbrella, that would be circumstantial evidence from which you could conclude that it was raining.

You should consider both types of evidence that are presented to you. The law makes no distinction in the weight to be given to either direct or circumstantial evidence. You are to decide how much weight to give any evidence.

Source: Third Circuit Model Civil Instruction 1.6.

INSTRUCTION NO. 7

In deciding what the facts are, you may have to decide what testimony you believe and what testimony you do not believe. You are the sole judges of the credibility of the witnesses. “Credibility” means whether a witness is worthy of belief. You may believe everything a witness says, or only part of it, or none of it. In deciding what to believe, you may consider a number of factors, including the following:

1. The opportunity and ability of the witness to see or hear or know the things the witness testifies to;
2. The quality of the witness’s understanding and memory;
3. The witness’s manner while testifying;
4. Whether the witness has an interest in the outcome of the case or any motive, bias, or prejudice;
5. Whether the witness is contradicted by anything the witness said or wrote before trial or by other evidence;
6. How reasonable the witness’s testimony is when considered in the light of other evidence that you believe; and
7. Any other factors that bear on believability.

The weight of the evidence to prove a fact does not necessarily depend on the number of witnesses who testify. What is more important is how believable the witnesses were, and how much weight you think their testimony deserves.

Source: Third Circuit Model Civil Instruction 1.7.

INSTRUCTION NO. 8

You will have the opportunity to ask questions of the witnesses in writing. When a witness has been examined and cross-examined by counsel, and after I ask any clarifying questions of the witness, I will ask whether any juror has any further clarifying question for the witness.

If so, you will write your question on a piece of paper, and hand it to my Deputy Clerk. Do not discuss your question with any other juror. I will review your question with counsel at sidebar and determine whether the question is appropriate under the rules of evidence. If so, I will ask your question, though I might put it in my own words. If the question is not permitted by the rules of evidence, it will not be asked, and you should not draw any conclusions about the fact that your question was not asked. Following your questions, if any, the attorneys may ask additional questions. If I do ask your question, you should not give the answer to it any greater weight than you would give to any other testimony.

Source: Third Circuit Model Civil Instruction 1.8.

INSTRUCTION NO. 9

If you wish, you may take notes during the presentation of evidence, the summations of attorneys at the conclusion of the evidence, and during my instructions to you on the law. My Courtroom deputy will arrange for pens, pencils, and paper. Remember that your notes are for your own personal use—they are not to be given or read to anyone else.

As you see, we have a court reporter here who will be transcribing the testimony during the course of the trial. But you should not assume that the transcripts will be available for your review during your deliberations. Nor should you consider notes that you or fellow jurors may take as a kind of written transcript. Instead, as you listen to the testimony, keep in mind that you will be relying on your recollection of that testimony during your deliberations. Here are some other specific points to keep in mind about note taking:

1. Note-taking is permitted, not required. Each of you may take notes. No one is required to take notes.
2. Be brief. Do not try to summarize all of the testimony. Notes are for the purpose of refreshing memory. They are particularly helpful when dealing with measurements, times, distances, identities, and relationships. Overuse of note-taking may be distracting. You must determine the credibility of witnesses; so you must observe the demeanor and appearance of each person on the witness stand. Note-taking must not distract you from that task. If you wish to make a note, you need not sacrifice the opportunity to make important observations. You may make your note after having made an observation.
3. Do not use your notes, or any other juror's notes, as authority to persuade fellow jurors. In your deliberations, give no more and no less weight to the views of a fellow juror just because that juror did or did not take notes. As I mentioned earlier, your notes are not official transcripts. They are not evidence, and they are by no means a complete outline of the proceedings or a list of the highlights in the trial. They are valuable, if at all, only as a way to refresh your memory. Your memory is what you should be relying on when it comes time to deliberate and render your verdict in this case. You therefore are not to use your notes as authority to persuade fellow jurors of what the evidence was during the trial. Notes are not to be used in place of the evidence.
4. Do not take your notes away from court. If you do take notes, take them with you each time you leave the courtroom and please leave them in

the jury room when you leave at night. At the conclusion of the case, after you have used your notes in deliberations, a court officer will collect and destroy them, to protect the secrecy of your deliberations.

Source: Third Circuit Model Civil Instruction 1.9.

INSTRUCTION NO. 10

This is a civil case. Relators are the parties who brought this lawsuit. Defendant is the party against which the lawsuit was filed. Relators have the burden of proving their case by what is called the preponderance of the evidence. That means Relators have to prove to you, in light of all the evidence, that what they claim is more likely so than not so. To say it differently: If you were to put the evidence favorable to Relators and the evidence favorable to Defendant on opposite sides of the scales, Relators would have to make the scales tip somewhat on their side. If Relators fail to meet this burden, the verdict must be for the Defendant. If you find after considering all of the evidence that a claim or fact is more likely so than not so, then the claim or fact has been proved by a preponderance of the evidence.

In determining whether any fact has been proved by a preponderance of evidence in the case, you may, unless otherwise instructed, consider the testimony of all witnesses, regardless of who may have called them, and all exhibits received in evidence, regardless of who may have produced them.

On certain issues, called affirmative defenses, Defendant has the burden of proving the elements of the defense by a preponderance of the evidence. I will instruct you on the facts that will be necessary for you to find on this affirmative defense. An affirmative defense is proven if you find, after considering all evidence in the case, that Defendant has succeeded in proving that the required facts are more likely so than not so.

You may have heard of the term “proof beyond a reasonable doubt.” That is a stricter standard of proof, and it applies only to criminal cases. It does not apply in civil cases such as this. So you should put it out of your mind.

Source: Third Circuit Model Civil Instruction 1.10.

INSTRUCTION NO. 11

The trial will proceed in the following manner:

First, attorneys for Relators will make an opening statement to you. Next, attorneys for the Defendant may make an opening statement. What is said in the opening statements is not evidence, but is simply an outline to help you understand what each party expects the evidence to show.

The Relators go first because they have the burden of proof. Relators will present witnesses whom counsel for the Defendant may cross-examine, and Relators may also present evidence. Following Relators' case, the Defendant may present evidence. Counsel for Relators may cross-examine witnesses for the defense. After the parties' main cases have been presented, Relators may then present what is called rebuttal evidence.

After all the evidence has been presented, I will instruct you on the law and then the attorneys will present to you closing arguments to summarize and interpret the evidence in a way that is helpful to their clients' positions. As with opening statements, closing arguments are not evidence. After that you will retire to the jury room to deliberate on your verdict in this case.

Source: Third Circuit Model Civil Instruction 1.12.

INSTRUCTION NO. 12

The rules of evidence permit the judge to accept facts that cannot reasonably be disputed. This is called judicial notice. I have decided to accept as proved the fact that *[state the fact that the court has judicially noticed]*, even though no evidence has been introduced to prove this fact. You must accept this fact as true for purposes of this case.

Source: Third Circuit Model Civil Instruction 2.2.

INSTRUCTION NO. 13

The parties have agreed that [*set forth stipulated facts*] are true. You must therefore treat these facts as having been proved for purposes of this case.

Source: Third Circuit Model Civil Instruction 2.4.

INSTRUCTION NO. 14

A deposition is the sworn testimony of a witness taken before trial. The witness is placed under oath and swears to tell the truth, and lawyers for each party may ask questions. A court reporter is present and records the questions and answers.

The deposition of [*name of witness*], which was taken on [*date*], is about to be presented to you by video. Deposition testimony is entitled to the same consideration and is to be judged, insofar as possible, in the same way as if the witness had been present to testify.

Source: Third Circuit Model Civil Instruction 2.5.

INSTRUCTION NO. 15

Evidence [will now be] [was] presented to you in the form of admissions to the truth of certain facts. These admissions were given in writing before the trial, in response to requests that were submitted under established court procedures. You must treat these facts as having been proved.

Source: Ninth Circuit Model Civil Instruction 2.12.

INSTRUCTION NO. 16

The Relators have presented exhibits in the form of charts and summaries. I decided to admit these charts and summaries in place of the underlying documents that they represent in order to save time and avoid unnecessary inconvenience. You should consider these charts and summaries as you would any other evidence.

Source: Third Circuit Model Civil Instruction 2.7.

INSTRUCTION NO. 17

Certain charts and summaries that have not been received in evidence have been shown to you in order to help explain or illustrate the contents of books, records, documents, testimony, or other evidence in the case. For example, you may see charts and summaries during the parties' opening and closing statements or during the testimony of opinion witnesses. Unless the charts or summaries were specifically admitted as trial exhibits, they are not themselves proof of any facts. They are not binding on you in any way. If they do not correctly reflect the facts shown by the evidence in the case, you should disregard these charts and summaries and determine the facts from the evidence.

Source: Third Circuit Model Instruction 2.8.

INSTRUCTION NO. 18

You will hear testimony containing opinions from [*expert witness*]. In weighing this opinion testimony, you may consider [*his/her*] qualifications, the reasons for [*his/her*] opinions, and the reliability of the information supporting those opinions, as well as the factors I have previously mentioned for weighing the testimony of any other witness. The opinion of [*name of witness*] should receive whatever weight and credit, if any, you think appropriate, given all the other evidence in the case.

In deciding whether to accept or rely upon the opinion of [*name of witness*], you may consider any bias that [*he/she*] may have, including any bias that may arise from evidence that [*he/she*] has been or will be paid for reviewing the case and testifying.

Source: Third Circuit Model Instruction 2.11.

INSTRUCTION NO. 19

We are about to take a recess. During this recess and any other recess, you must not discuss this case with anyone, including your fellow jurors, members of your family, people involved in the trial, or anyone else. If anyone tries to talk to you about the case, do not tell your fellow jurors but tell me about it immediately. Do not read, watch or listen to any news reports of the trial, or conduct any research or investigation, including on the Internet. Remember that I told you not to use any electronic tools to communicate with anyone about the case or to do research relating to the case. Finally, remember to keep an open mind until all the evidence has been received and you have heard the views of your fellow jurors.

If you need to speak with me about anything, simply give a signed note to [identify court personnel] to give to me.

Source: Third Circuit Model Instruction 2.14.

INSTRUCTION NO. 20

Defendant Janssen is a corporation. A corporation acts only through its agents or employees, and any agent or employee of a corporation may bind the corporation when acting within the scope of the authority delegated to the agent by the corporation, or within the scope of his or her duties as an employee of the corporation.

Source: *United States ex rel. Jones v. Brigham and Women's Hosp.*, 678 F.3d 72, 82 n.18 (1st Cir. 2012) (“We have long held that corporate defendants may be subject to FCA liability when the alleged misrepresentations are made while the employee is acting within the scope of his or her employment.”); *see also A.S.M.E. v. Hydrolevel Corp.*, 456 U.S. 556, 566 (1982) (applying agency principles to impute knowledge of corporate employees to their employer); *see also United States v. Anchor Mortg. Corp.*, 711 F.3d 745, 747–48 (7th Cir. 2013).

INSTRUCTION NO. 21

In this case, Relators seek recovery from Defendant under the federal and state False Claims Acts. Relators allege that Defendant is liable under the False Claims Acts due to its alleged off-label marketing. Relators also allege that Defendant is liable under the False Claims Acts due to alleged violations of the Anti-Kickback Statute.

Relators allege that Defendant caused the submission of false claims in multiple, independent ways.

First, in determining whether a claim is false, you must consider that government health care programs, including Medicare, Medicaid, and ADAP, will only cover and pay for a drug that (1) is used for a “medically accepted indication,” which means any FDA-approved use on the label that is supported by one or more citations in certain drug compendia; *and* (2) is “reasonable and necessary for the diagnosis or treatment of illness or injury.” The government only pays for prescriptions that satisfy both of these requirements. Thus, a drug that is not prescribed for “a medically accepted indication,” or is either unreasonable or unnecessary, is ineligible for reimbursement by the government and, therefore, false under the FCA.

Second, a claim is also false if the Defendant violated the Anti-Kickback Statute in connection with the claim. I will now explain to you the elements of the Anti-Kickback Statute.

Source: *Gohil*, 500 F. Supp. 3d at 357; 42 U.S.C. § 1395w-102(e)(1); 42 U.S.C. § 1395y(a)(1)(A); 42 U.S.C. §§ 1396r-8(d)(1)(B)(i), (g)(1)(B)(i) and (k)(6); *See United States ex rel. Bergman v. Abbott Labs.*, 995 F. Supp. 2d 357, 367 (E.D. Pa. 2014)(prescriptions for uses that are “‘not reasonable and necessary for treatment,’ makes those uses ineligible for reimbursement under Medicare and Medicaid regulations.”); *United States ex rel. Strom v. Scios, Inc.*, 676 F. Supp. 2d 884, 891 (N.D. Cal. 2009) (Because CMS “permits reimbursement only for ‘reasonable and necessary’ treatments, a prescription of [a drug] in a context where it is not ‘reasonable’ or ‘necessary’ would be statutorily ineligible for reimbursement.”); *United States ex rel. Polukoff v. St. Mark’s Hospital*, 895 F.3d 730, 742 (10th Cir. 2018) (in an FCA case involving eligibility for payment under Medicare, “a claim is false if it is not reimbursable, and a Medicare claim is not reimbursable if the services provided were not medically necessary”); *Diamond v. Sec’y of Health & Hum. Servs.*, No. 1:13 CV 2481, 2015 WL 367010, at *6 (N.D. Ohio Jan. 27, 2015) (holding in a Medicare Part D coverage case that the “relevant

statutes create two coverage requirements under Part D”—that the medication be ““reasonable and necessary”” for the patient and “prescribed for a ‘medically accepted indication’”); *United States ex rel. Fesenmaier v. Cameron-Ehlen Grp., Inc.*, Case No. 13-CV-3003, Dkt 982 at 110 (D. Minn. Feb. 28, 2023) (Final Jury Instructions); 42 U.S.C. § 1320(a)-7b(g)(a violation of the AKS constitutes a “false or fraudulent claim” under the FCA); *see United States ex rel. Penelow*, 2021 WL 6052425, at *5 (citing 42 U.S.C. § 1395w-102(e)(3); 42 U.S.C. § 1395y(a)(I)(A)) (Quraishi, J.); *United States ex rel. Penelow v. Johnson & Johnson, et al.*, 2017 WL 2367050, *4 (D.N.J. May 31, 2017) (Shipp, J.); *see also* 42 U.S.C. §§ 1395w-102(e)(1), (e)(3); 42 U.S.C. § 1395y(a)(l)(A); 42 C.F.R. § 411.15(k)(1).

INSTRUCTION NO. 22

I instruct you that any claims submitted to a government health care program resulting from a violation of the Anti-Kickback Statute is a false claim under the False Claims Act. Therefore, for the kickback claims, in determining whether Defendant violated the False Claims Act, you will first have to determine whether Defendant violated the Anti-Kickback Statute.

For you to find that Defendant violated the Anti-Kickback Statute, Relators must prove each of the following elements by a preponderance of the evidence.

First, that Defendant offered or paid any remuneration, including any kickback or bribe directly or indirectly, openly or secretly, in cash or in kind.

Second, that one purpose of the remuneration offered or paid was to induce or reward prescriptions of Prezista or Intelence.

Third, that payments for those prescriptions of Prezista or Intelence may have been made, in whole or in part, by a federal health care program.

Fourth, that Defendant acted knowingly and willfully.

I will now provide you with further explanation of each of these elements.

The first element of the Anti-Kickback Statute that Relators must prove by a preponderance of the evidence is that Defendant offered or paid remuneration. "Remuneration" means the transfer of anything of value from one person or entity to another person or entity. Remuneration can be direct or indirect, overt or covert, in cash or can include anything of value in any form whatsoever.

The second element of the Anti-Kickback Statute that Relators must prove by a preponderance of the evidence is that one of the purposes of the remuneration was to induce or reward the referral, purchase, order, recommendation of any item or service paid for by a federal health care program. It is not a defense that there might have been some other reason for the remuneration if you find by a preponderance of the evidence that one of the purposes of the remuneration to induce or reward the referral, purchase, order, recommendation of any item or service to be paid for by the federal health care program. Unlawful inducement does not need to be the primary purpose of the remuneration.

The third element of the Anti-Kickback Statute that Relators must prove by a preponderance of the evidence is that the item furnished by Defendant as a result of

the alleged inducement was covered in whole or in part by a federal health care program. The term “federal health care program” means any plan or program that provides health benefits and is funded entirely or indirectly by the United States government. I instruct you that Medicare, Medicaid, and ADAP are “federal health care programs.”

The fourth element of the Anti-Kickback Statute that Relators must prove by a preponderance of the evidence is that Defendant acted knowingly and willfully in offering or providing the remuneration. An act is done “knowingly” for purposes of the Anti-Kickback Statute if the act is done voluntarily and intentionally, and not because of a mistake or accident. The term “willfully” means acting with a purpose to disobey or disregard the law. An act is done “willfully” if Defendant knew that the act was unjustifiable or wrong, even if Defendant was not aware of the specific law or rule that they may have been violating. Relators do not have to prove that Defendant specifically intended to violate the Anti-Kickback Statute.

Source: 42 U.S.C. § 1320(a)-7b(b)(2); *United States v. Goldman*, Case No. 2:12-cr-00305-ER, Dkt. 88 at 18–21 (E.D. Pa. May 31, 2013) (Final Charge of the Court); *United States v. Bennett*, 688 Fed. App’x 169, 171 n.3 (3d Cir. 2017) (appeal from D.N.J.) (finding no error where the “District Court instructed the jury that ‘a kickback means any money, fee, commission, credit, gift, gratuity, thing of value, or compensation of any kind that is provided to a prime contractor . . . to improperly obtain or reward favorable treatment in connection with a prime contract’”); *Gohil*, 500 F. Supp. 3d at 359 (holding the AKS requires the plaintiff prove “at least one purpose of the remuneration was to induce prescriptions or referrals” but “does not need to prove this was the only purpose”) (citing *United States v. Greber*, 760 F.2d 68, 72 (3d Cir. 1985)); *Bartlett*, 39 F. Supp. 3d at 678 (quoting OIG Supp. Compliance Program Guidance for Hospitals, 70 Fed. Reg. 4858, 4864 (Jan. 31, 2005) (“Importantly, under the Anti-Kickback Statute, neither a legitimate business purpose for the arrangement, nor a fair market value payment, will legitimize a payment if there is also an illegal purpose (i.e., inducing Federal health care program business.”)); *United States v. Goldman*, 607 Fed. App’x 171, 174–75 (3d Cir. 2015) (“The District Court correctly instructed the jury on willfulness.”); *United States ex rel. Fesenmaier v. Cameron-Ehlen Grp., Inc.*, Case No. 13-CV-3003, Dkt 982 at 11 (D. Minn. Feb. 28, 2023) (Final Jury Instructions); *Klaczak v. Consol. Med. Transp.*, 458 F. Supp. 2d 622, 674 (N.D. Ill. 2006) (citing Seventh Circuit Federal Criminal Jury Instructions on “knowingly” in discussion of AKS standard); *McCormick v. Maquet Cardiovascular US Sales LLC*, No. 2:15-CV-7670-KM-MAH, 2018 WL 3696572, at *10 (D.N.J. Aug. 3, 2018); 42 U.S.C. § 1320(a)-7b(h).

INSTRUCTION NO. 23

As explained earlier, Relators allege that Defendant is liable under the federal False Claims Act stemming from its alleged off-label marketing, and stemming from its alleged violations of the Anti-Kickback Statute. Therefore, the next thing that you will have to consider is whether Defendant is liable under the False Claims Act.

For you to find that Defendant is liable under the federal False Claims Act, Relators must prove the following elements by a preponderance of the evidence: (1) falsity; (2) causation; (3) scienter, which means culpable state of mind; and (4) materiality.

I will now explain each of these elements in turn.

First, Relators must prove by a preponderance of the evidence that the claims submitted or caused to be submitted by Defendant were false. I have instructed you that a claim resulting from a violation of the Anti-Kickback Statute is false.

Second, Relators must prove by a preponderance of the evidence that Defendant caused the claims to be submitted to the federal government. Defendant's conduct may be found to have caused the submission of a claim for Medicare, Medicaid, or ADAP reimbursement if the conduct was either (1) a substantial factor in inducing providers to submit claims for reimbursement, and (2) if the submission of claims for reimbursement was reasonably foreseeable or anticipated as a natural consequence of defendants' conduct.

Third, Relators must prove by a preponderance of the evidence that Defendant acted knowingly. "Knowingly" means the Defendant had actual knowledge, acted with deliberate ignorance to the truth or falsity of their statements, or recklessly disregarded the truth or falsity of the information. Relators are not required to show proof of specific intent to defraud.

Fourth, Relators must prove by a preponderance of the evidence that Defendant's alleged Anti-Kickback Statute or off-label marketing violations were material to the Government's payment decision. "Material" means that it had a natural tendency to influence, or was capable of influencing, the payment or receipt of money or property.

Source: 31 U.S.C. § 3729(a)(1)(A) and (B), (b)(1) and (4); *Gohil*, 500 F. Supp. 3d at 358–62; 42 U.S.C. § 1320a-7b(g); *United States ex rel. Fesenmaier v. Cameron-Ehlen Grp., Inc.*, Case No. 13-CV-3003, Dkt 982 at 12–13 (D. Minn. Feb. 28, 2023)

(Final Jury Instructions); *Ruckh v. Salus Rehab., LLC*, 963 F.3d 1089, 1107 (11th Cir. 2020); *Purcell v. Gilead Scis., Inc.*, 439 F. Supp. 3d 388, 398 (E.D. Pa. 2020) (“Compliance with the anti-kickback statute is a material condition of payment under the False Claims Act.”); *United States ex rel. Miller v. Weston Educ., Inc.*, 840 F.3d 494, 503 (8th Cir. 2016).

INSTRUCTION NO. 24

In addition to the federal False Claims Act, Relators also assert claims on behalf of the States of New Jersey, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Washington, and the District of Columbia under their versions of the False Claims Act. These State False Claims Acts allow Relators like Ms. Penelow and Ms. Brancaccio to bring a lawsuit on behalf of a state government.

Earlier, I gave you instructions about the law applicable to the federal False Claims Act and Anti-Kickback Statute. Those instructions apply to the States' claims as well. Each of the States operates a Medicaid program with state and federal funds. As a result, the Anti-Kickback Statute is one of the laws that is applicable to these Medicaid programs.

Most States' False Claims Acts are modeled on the federal False Claims Act and have very similar or identical provisions. These State False Claims Acts impose liability on a defendant that knowingly presents, or causes to be presented, a false or fraudulent claim for payment. Therefore, if after following my earlier instructions, you found that Defendant violated the federal False Claims Act, you must also find that Defendant violated the analogous provisions of all of the States' False Claims Acts, except I will provide separate instructions for Texas.

Accordingly, if you find Defendant liable under the standards explained earlier for the False Claims Act as to any Medicaid reimbursements in a particular State (other than Texas), then you should find that Defendant is also liable under that State's law. Conversely, if you find that Defendant is not liable under the False Claims Act for any Medicaid reimbursements in a particular State, then you should find that Defendant is not liable under that State's law.

Source: James B. Helmer, Jr., *THE FALSE CLAIMS ACT: WHISTLEBLOWER LITIGATION*, at 931–32 (8th ed. 2021) (“Helmer Treatise”) (setting forth model language for instructing the jury on state False Claims Acts in FCA cases based on instructions proposed by the Government in *United States ex rel. Kester v. Novartis Pharm. Corp.*, No. 1:11-cv-08196, Dkt 476 (S.D.N.Y. July 2, 2015)); Cal. Gov. Code 12651 *et seq.* (California); Colo. Rev. Ann. §§ 25.5-4-305 *et seq.* (Colorado); Conn. Gen. Stat. § 4-275(a) (Connecticut); Del. Code Ann. tit. 6 §§ 1201 *et seq.* (Delaware); Fla. Stat. §§ 68.082 *et seq.* (Florida); Ga. Code Ann. §§ 49-4-168 *et seq.*

(Georgia); Haw. Rev. Stat. §§ 661-21 *et seq.* (Hawaii); 740 Ill. Comp. Stat. § 175/3 *et seq.* (Illinois); Ind. Code §§ 5-11-5.5-2 *et seq.* (Indiana); Iowa Code §§ 685.2 *et seq.* (Iowa); La. Rev. Stat. Ann. §§ 46:438.1 *et seq.* (Louisiana); Mass. Gen. Laws ch. 12, § 5B *et seq.* (Massachusetts); Mich. Comp. Laws §§ 400.607 *et seq.* (Michigan); Minn. Stat. §§ 15C.02 *et seq.* (Minnesota); Mont. Code Ann. §§ 17-8-401 *et seq.* (Montana); N.J. Rev. Stat. § 2A:32C-3 (New Jersey); N.M. Stat. §§ 27-14-4 *et seq.* (New Mexico); Nev. Rev. Stat. §§ 357.040 *et seq.* (Nevada); N.Y. State Fin. Law §§ 189 *et seq.* (New York); N.C. Gen. stat. §§ 1-607 *et seq.* (North Carolina); Okla. Stat. tit. 63 §§ 5053 *et seq.* (Oklahoma); R.I. Gen. Laws §§ 9-1.1-3 *et seq.* (Rhode Island); Tex. Hum. Res. Code §§ 36.001 *et seq.* (Texas); Tenn. Code Ann. §§ 71-5-181 *et seq.* (Tennessee); Va. Code §§ 8.01–216.1 *et seq.* (Virginia); Wash. Rev. Code §§ 74.66.005 *et seq.* (Washington); D.C. Code §§ 2-381.01 *et seq.* (District of Columbia); *see, e.g.*, *New York v. Amgen Inc.*, 652 F.3d 103, 112–13 (1st Cir. 2011) (finding that statutes and regulations in Massachusetts, Illinois and California, among other states, “make clear that the kickbacks alleged in this case preclude Medicaid payment”); *United States v. Loving Care Agency, Inc.*, 226 F. Supp. 3d 357, 363–64 (D.N.J. 2016) (“The language in the NJFCA is nearly identical to the federal statute and thus requires the same showings[.]”).

INSTRUCTION NO. 25

For Texas, you should follow the instructions I gave in connection with the federal False Claims Act, except as modified by the instructions I will now give you.

Defendant is liable under the Texas False Claims Act if you find that, by a preponderance of the evidence, Relators established that Defendant knowingly violated the Texas anti-kickback law. The Texas anti-kickback law makes it illegal to offer or pay, directly or indirectly, in cash or in kind to induce a person to refer an individual to another person for the furnishing of, or for arranging the furnishing of, any item or service for which payment may be made, in whole or in part, under the medical assistance program.

The term “knowingly” as used in the Texas False Claims Act means that the defendant (1) had knowledge of the information; (2) acted with conscious indifference to the truth or falsity of the information; or (3) acted in reckless disregard of the truth or falsity of the information.

Source: Tex. Hum. Res. Code §§ 32.039(b)(1-c), (a)(4); Helmer Treatise, *supra* at 932–34 (providing model instruction for Texas False Claims Act).

INSTRUCTION NO. 26

If you find that Defendant violated the False Claims Act or its State analogues, then you must assess damages.

I will now explain the law related to damages. However, the fact that I am instructing you on the issue of damages should not be taken to mean that I have any view on whether you should find liability. If you do not find Defendant liable, then you should not assess any damages.

Relators must prove the Government's damages with reasonable certainty. You may not award damage that are speculative—that is, damages that might be possible but are based solely on guesswork. Relators are not required to prove the exact amount of damages, but Relators must show sufficient facts and circumstances to permit you to make a reasonable estimate of the damages.

Source: Joel M. Androphy, *Federal False Claims Act and Qui Tam Litigation* § 11.08 (2013) (citing *United States v. Killough*, 848 F.2d 1523, 1531 (11th Cir.1988)); *see also* John T. Boese, Civil False Claims and Qui Tam Actions, *Appendix F: Sample Jury Instructions (2) in a Reverse False Claim Case*.

INSTRUCTION NO. 27

The measure of damages under the False Claims Act is the amount of money that the Government paid out by reason of the false claims.

If you find that Defendant submitted false claims or caused false claims to be submitted to a federal health care program during the damages period, then the full amount paid to Defendant as the result of those false claims is the amount of damages.

To account for the various State analogues to the False Claims Act, you must differentiate between damages suffered by the United States, the twenty-six states, and the District of Columbia. Accordingly, the verdict form will ask you to specify the amount of damages (if any) that you attribute to the United States, the twenty-six states, and the District of Columbia.

Source: *United States v. Teva Pharmas. USA, Inc.*, 2023 WL 4565105, *5–6 (D. Mass. July 14, 2023) (collecting cases) (concluding that “the Court will measure damages in this case as the entirety of the government’s payments for the claims resulting from the illegal kickbacks,” and explaining that “the rationale here is that the government simply would not have paid those Medicare claims had it known they were submitted in violation of certain Medicare requirements such as the AKS”); *see also United States v. Cameron-Ehlen Grp., Inc.*, 2023 WL 36174, at *3 (D. Minn. Jan. 4, 2023); *United States v. Novak*, 2018 WL 4205540, at *4 (N.D. Ill. Sept. 4, 2018); *Yates v. Pinnellas Hematology & Oncology, P.A.*, 21 F.4th 1288, 1304 (11th Cir. 2021); *United States v. Rogan*, 517 F.3d 449, 453 (7th Cir. 2008); *United States ex rel. Longhi v. United States*, 575 F.3d 458, 473 (5th Cir. 2009); *see also United States ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 386 (4th Cir. 2015).

INSTRUCTION NO. 28

Any money recovered under the federal False Claims Act or the state analogues goes to the United States and the States. The United States and the States may then provide the Relators with a portion of that recovery. You are not to allow the possibility of a relator's share of the recovery to enter into your deliberations about whether, or the extent to which, the United States and the States are entitled to monetary damages.

Source: *Roberts v. Accenture, Ltd. Liab. P'ship*, 707 F.3d 1011, 1017–18 (8th Cir. 2013) (noting that a relator's share of recovery under the FCA “only comes into play at the conclusion of a case, after the action has already proceeded to a judgment or settlement”); *United States ex rel. Shutt v. Cnty. Home and Health Serv, Inc.*, 550 F.3d 764, 766 (9th Cir. 2008) (“The criteria for determining the relator's share . . . generally are not relevant to the defendant's liability under the FCA.”).

INSTRUCTION NO. 29

If you find that Defendant violated the False Claims Act, then you must also identify the number of false or fraudulent claims that were submitted to the United States, the States, and the District of Columbia.

Again, the fact that I am instructing you on the issue of the number of false claims should not be taken to mean that I have any view on whether you should find liability. If you do not find Defendant liable under the False Claims Act, then you should not assess the number of false claims.

Source: 31 U.S.C. § 3729(a); *see also United States v. Bornstein*, 423 U.S. 303, 309 n.4 (1976) (explaining that “the number of imposable forfeitures has generally been set at the number of individual payment demands that the contractor has made upon the Government”); Jury Instructions in *United States ex rel. Drakeford v. Tuomey*, No. 3:05-2858-MBS, Doc. No. 810 at 15 (D.S.C. May 8, 2013); Jury Instructions in *United States v. Berkeley Heartlab Inc.*, No. 9:14-cv-00230-RMG, at 32 (D.S.C. Nov. 27, 2017) (Doc. No. 755); Jury Instructions in *United States ex rel. Bunk v. Birkart Globistics GMBH & Co.*, No. 1:02-cv-1168, Doc. No. 1312-3 at 53 (E.D. Va. Aug. 1, 2014); Jury Instructions in *United States v. AllQuest Home Mortgage Corp.*, No. 4:12-cv-2676, Doc. No. 434 at 7 (S.D. Tex. Nov. 18, 2016); *United States ex rel. Marcus v. Hess*, 317 U.S. 537 (1943); *United States ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 386 (4th Cir. 2015).

INSTRUCTION NO. 30

When you retire to the jury room to deliberate, you may take with you the instructions I have just given you, your notes, and the exhibits that the Court has admitted into evidence. You should select one member of the jury as your foreperson. That person will preside over the deliberations and speak for you here in open court.

As jurors, you have a duty to consult with each other and to deliberate with the intention of reaching a verdict. Each of you must decide the case for yourself, but only after a full and impartial consideration of all of the evidence with your fellow jurors. Listen to each other carefully. In the course of your deliberations, you should feel free to re-examine your own views and to change your opinion based upon the evidence. But you should not give up your honest convictions about the evidence just because of the opinions of your fellow jurors. Nor should you change your mind just for the purpose of obtaining enough votes for a verdict.

When you start deliberating, do not talk to the jury officer, to me or to anyone but each other about the case. During your deliberations, you must not communicate with or provide any information to anyone by any means about this case. You may not use any electronic device or media, such as a cell phone, smart phone, or computer of any kind; the internet, any internet service, or any text or instant messaging service; or any internet chat room, blog, website, or social networking service, to communicate to anyone any information about this case or to conduct any research about this case until I accept your verdict.

You may not use these electronic means to investigate or communicate about the case because it is important that you decide this case based solely on the evidence presented in this courtroom. Information on the internet or available through social media might be wrong, incomplete, or inaccurate. Information that you might see on the internet or on social media has not been admitted into evidence and the parties have not had a chance to discuss it with you. You should not seek or obtain such information and it must not influence your decision in this case.

If you have any questions or messages for me, you must write them down on a piece of paper, have the foreperson sign them, and give them to the jury officer. The officer will give them to me, and I will respond as soon as I can. I may have to talk to the lawyers about what you have asked, so it may take some time to get back to you.

One more thing about messages. Never write down or tell anyone how you stand on your votes. For example, do not write down or tell anyone that a certain

number is voting one way or another. Your votes should stay secret until you are finished.

Your verdict must represent the considered judgment of each juror. In order for you as a jury to return a verdict, each juror must agree to the verdict. Your verdict must be unanimous.

A form of verdict has been prepared for you. It has a series of questions for you to answer. You will take this form to the jury room and when you have reached unanimous agreement as to your verdict, you will fill it in, and have your foreperson date and sign the form. You will then return to the courtroom and your foreperson will give your verdict. Unless I direct you otherwise, do not reveal your answers until you are discharged. After you have reached a verdict, you are not required to talk with anyone about the case unless I order you to do so.

Once again, I want to remind you that nothing about my instructions and nothing about the form of verdict is intended to suggest or convey in any way or manner what I think your verdict should be. It is your sole and exclusive duty and responsibility to determine the verdict.

Source: Third Circuit Model Civil Instruction 3.1.

Date: April 19, 2024

Respectfully submitted,

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